



International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

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July 6, 1999

The Dockets Management Branch (HFS - 300)
Food and Drug Administration
5630 Fisher Lane
Room 1061
Rockville, MD 20852

Dear Sir/Madam:

RE: Docket No. 99N-1076

Risk Assessment of the Public Health Impact of Foodborne *Listeria Monocytogenes*; Request for Comments and for Scientific Data and Information.

These comments are submitted on behalf of the International Dairy Foods Association (IDFA), and its constituent organizations the Milk Industry Foundation, the International Ice Cream Association and the National Cheese Institute. The approximately 850 member companies of these associations operate more than 1200 processing and manufacturing plants, which account for 85 percent of all dairy products consumed in the United States.

IDFA strongly supports the efforts of the Food and Drug Administration (FDA) in consultation with the U.S. Department of Agriculture's Food Safety and Inspection Service (USDA/FSIS) in conducting a risk assessment to determine the prevalence and extent of exposure of consumers to foodborne *Listeria monocytogenes* and to assess the resulting public health impact of such exposure. There is a clear need to review the current validity of the regulatory policy of "zero tolerance" for *Listeria monocytogenes* in ready-to-eat foods. This risk assessment will, hopefully, serve as a basis to provide sound scientific evidence for a departure from the "zero tolerance" policy that will not pose any increased risk to public health.

The dairy industry recognizes the seriousness of *Listeria* as a foodborne human pathogen. Understanding that raw foods such as unpasteurized milk can contain *Listeria monocytogenes* and pasteurization has been demonstrated to effectively destroy the organism, the dairy industry has undertaken extensive changes in dairy product processing to minimize any potential for contamination of product after the pasteurization step. The dairy industry worked in cooperation with FDA to develop "Recommended Guidelines, for Controlling Environmental and Product Contamination in Dairy Plants" which was published/released in September 1986. These guidelines have been successfully used in combination with strict adherence to basic sanitation principles and good manufacturing practices and are incorporated as part of our industry's

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prerequisite for a dairy product HACCP program. Moreover, this initiative was successful with respect to significantly lowering the frequency of which *Listeria monocytogenes* was found in dairy plant environments and in finished products. More importantly in examining the exposure to humans from the total food supply, data reported by the Center for Disease Control and Prevention (CDC) indicate the incidence of listeriosis dropped approximately forty four (44%) between 1989 and 1993.¹

However, even when the incidence rate of listeriosis was dropping, government surveillance and testing of ready-to-eat food found positive findings, resulting in Class I recalls on products such as cheeses, ice cream, milk, prepared salads, sandwiches, smoked fish, meats, shellfish, and bakery products. Between 1987 and 1992 there were 970 products subject to recalls for *Listeria monocytogenes* of which 28 were for dairy products, and 12 for cheeses.² The cost associated with these recalls of dairy products is estimated to be in the billions of dollars, in spite of the fact that many of those recalls involved ice cream and frozen deserts which have not been positively linked to listeriosis in humans.

In recognizing that the total elimination of *Listeria* from all foods is virtually impossible, many countries such as Canada, Denmark, Italy, France, Germany, and The Netherlands have established tolerance, for low levels of *Listeria monocytogenes* in ready-to-eat foods. The reported incidence rate for listeriosis of 0.5/100,000 population is similar in countries that have a “zero tolerance” policy and in those that have an established quantitative tolerance.

Additionally, the Codex Committee on Food Hygiene (CCFH) has been reviewing recommendations on *Listeria monocytogenes* and the International Commission on Microbial Specifications for Foods (ICMSF) has prepared draft standards to allow up to 100 organisms per gram in food at consumption, provided the food is not intended for consumption by high risk individuals.

It is suggested that the first step of addressing a change in regulatory policy to establish a tolerance for *Listeria monocytogenes* is to conduct a microbial risk assessment. We applaud the efforts of the FDA and USDA/FSIS in carrying out a ranking risk assessment to analyze epidemiological data of foodborne listeriosis, gather information on the level of *Listeria monocytogenes* contamination in foods and consumption levels, and assess information regarding human health consequences of exposure to this organism.

IDFA is committed to providing data and information to assist FDA and USDA/FSIS with the *Listeria monocytogenes* risk assessment. We strongly believe that relying only on the available data from past outbreaks, product recalls and scientific literature may not give an accurate picture of the level of *Listeria monocytogenes* contamination in the U.S. food supply. In addition, including data from foods produced outside the United States may not accurately

1 Tappero, J.W Et.AL: Reduction in incidence of human listeriosis in

United States: JAMA 1995, Apr.12:273(14): 1118-22.

2 Ryser, ET and Martin, EH, Eds: *Listeria, Listeriosis and Food Safety* – 2nd ed.;

New York: Marcel Dekker, Inc. 1999.

represent the current commercial manufacturing processes undertaken in the U.S. For example, some foreign countries do not require milk used in the manufacturing of cheese to be subjected to pasteurization or subsequent aging of the cheese.

In an effort to assist FDA with data collection for the risk assessment, IDFA will be providing data and information in two specific areas:

- 1) A summary of "blinded" historical finished product testing data from the past five years, on ice cream and frozen desserts, for the presence of *Listeria monocytogenes* and, where available, quantitative analysis.
- 2) A review of current commercial cheese manufacturing practices, which will include estimates of volume of each variety of cheese manufactured, and amounts of each cheese variety that is produced from raw, unpasteurized milk, heat treated milk, or pasteurized milk.

This data is currently being compiled by IDFA and we anticipate that this data will be submitted to the FDA's *Listeria* Risk Assessment Team by September 1, 1999.

IDFA appreciates the opportunity to respond to FDA's public notice requesting comments and scientific data and information.. Please contact me if you have any additional questions or if further clarification is necessary. We would be pleased to discuss any of our comments with the relevant agencies

Sincerely,



Cary P. Frye
Vice President, Scientific &
Regulatory Affairs

cc: R. Whiting

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